

L-ORAL PARACETAMOL SYRUP- paracetamol syrup
GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

L-Oral PARACETAMOL SYRUP

DRUG FACTS

Active ingredient

Paracetamol 160 mg

Purpose

Pain reliever - Fever reducer

INACTIVE INGREDIENTS

Artificial flavour, Methylparaben, Propylparaben, Potassium sorbate, Citric Acid Monohydrate, Sorbitol, Propylene glycol, Sucralose, Povidone K30, Glycerin, FD&C Red #40, D&C Red #33 & Purified water.

USES

Temporarily relieves minor aches and pains due to:

• The common cold • Flu • Headache • Sore throat • Toothache • Temporarily reduces fever

WARNINGS

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes: • More than 5 doses in 24 hours, which is the maximum daily amount • With other drugs containing acetaminophen

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: • Skin reddening • Blisters • Rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use • With any other product containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a

doctor or pharmacist • If your child is allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if your child has liver disease

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

When using this product, do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

• Pain gets worse or last for more than 5 days • Fever gets worse or last for more than 3 days • New symptoms occur • Redness or swelling is present
These could be signs of a serious condition.

Keep out of the reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

DIRECTIONS

• This product does not contain directions or complete warnings for adult use • Find right dose on chart. If possible, use weight to dose; otherwise, use age • mL = milliliter • If needed, repeat dose every 4 hours • Do not use more than 5 doses in 24 hours • Use enclosed dosing cup only. Do not use any other device

Weight	Age	Dose
under 24 lbs	Under 2 years	Ask a doctor
24 to 35 lbs	2 to 3 years	5mL
36 to 47 lbs	4 to 5 years	7.5mL
48 to 59 lbs	6 to 8 years	10mL
60 to 71 lbs	9 to 10 years	12.5mL
72 to 95 lbs	11 years	15mL

OTHER INFORMATION

• **TAMPER EVIDENT:** Do not use this product if inner foil seal over mouth of the bottle is cut, torn, broken, or missing.

• Store at 20° - 25°C (68° - 77°F)

• This product is not the same concentration as Infants' Drops. For accurate dosing,

follow the dosing instructions on this label.

QUESTIONS OR COMMENTS?

Call toll-free 1-800-572-6632, Weekdays 7:00 AM - 5.30 PM EST.

✓ **Fever reducer - Pain reliever**

✓ **Alcohol Free**

✓ **Aspirin Free**

Manufactured by :


Global Pharma Healthcare Pvt. Ltd.,

A-9, SIDCO Pharmaceutical Complex,

Alathur-603 110 - INDIA.

www.global-pharma.com

Packaging

<p>DRUG FACTS</p> <p>Active ingredient Paracetamol 160 mg</p> <p>Purpose Pain reliever - Fever reducer</p> <p>INACTIVE INGREDIENTS Artificial flavour, Methylparaben, Propylparaben, Potassium sorbate, Citric Acid Monohydrate, Sorbitol, Propylene glycol, Sucralose, Povidone K30, Glycerin, FD&C Red #40, D&C Red #33 & Purified water.</p> <p>USES Temporarily relieves minor aches and pains due to: ■ The common cold ■ Flu ■ Headache ■ Sore throat ■ Toothache ■ Temporarily reduces fever</p> <p>WARNINGS Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes: ■ More than 5 doses in 24 hours, which is the maximum daily amount ■ With other drugs containing acetaminophen</p> <p>Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: ■ Skin reddening ■ Blisters ■ Rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.</p> <p>Do not use ■ With any other product containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist ■ If your child is allergic to acetaminophen or any of the inactive ingredients in this product</p> <p>Ask a doctor before use if your child has liver disease</p> <p>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin</p> <p>When using this product, do not exceed recommended dose (see overdose warning)</p>	<p>DRUG FACTS (continued)</p> <p>Stop use and ask a doctor if ■ Pain gets worse or last for more than 5 days ■ Fever gets worse or last for more than 3 days ■ New symptoms occur ■ Redness or swelling is present</p> <p>These could be signs of a serious condition.</p> <p>Keep out of the reach of children.</p> <p>Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.</p> <p>DIRECTIONS ■ This product does not contain directions or complete warnings for adult use ■ Find right dose on chart. If possible, use weight to dose; otherwise, use age ■ mL = milliliter ■ If needed, repeat dose every 4 hours ■ Do not use more than 5 doses in 24 hours ■ Use enclosed dosing cup only. Do not use any other device</p> <table border="1"><thead><tr><th>Weight</th><th>Age</th><th>Dose</th></tr></thead><tbody><tr><td>under 24 lbs</td><td>Under 2 years</td><td>Ask a doctor</td></tr><tr><td>24 to 35 lbs</td><td>2 to 3 years</td><td>5mL</td></tr><tr><td>36 to 47 lbs</td><td>4 to 5 years</td><td>7.5mL</td></tr><tr><td>48 to 59 lbs</td><td>6 to 8 years</td><td>10mL</td></tr><tr><td>60 to 71 lbs</td><td>9 to 10 years</td><td>12.5mL</td></tr><tr><td>72 to 95 lbs</td><td>11 years</td><td>15mL</td></tr></tbody></table> <p>OTHER INFORMATION ■ TAMPER EVIDENT: Do not use this product if inner foil seal over mouth of the bottle is cut, torn, broken, or missing. ■ Store at 20°-25°C (68°-77°F) ■ This product is not the same concentration as Infants' Drops. For accurate dosing, follow the dosing instructions on this label.</p> <p>QUESTIONS OR COMMENTS? Call toll-free 1-800-572-6632, Weekdays 7:00 AM - 5.30 PM EST.</p>	Weight	Age	Dose	under 24 lbs	Under 2 years	Ask a doctor	24 to 35 lbs	2 to 3 years	5mL	36 to 47 lbs	4 to 5 years	7.5mL	48 to 59 lbs	6 to 8 years	10mL	60 to 71 lbs	9 to 10 years	12.5mL	72 to 95 lbs	11 years	15mL	<p>NDC 73921-026-04 L-Oral</p> <p>PARACETAMOL SYRUP</p> <p>4 FL OZ (118ml)</p> <p>Global Pharma</p> <p>✓ Fever reducer - Pain reliever ✓ Alcohol Free ✓ Aspirin Free</p>	<p>Mfg. Lic. No. : TN 00002175</p> <p>Batch No. : _____</p> <p>Mfg. Date : _____</p> <p>Exp. Date : _____</p> <p></p> <p>Manufactured by : Global Pharma Healthcare Pvt. Ltd., A-9, SIDCO Pharmaceutical Complex, Alathur-603 110 - INDIA. www.global-pharma.com</p>
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L-ORAL PARACETAMOL SYRUP

paracetamol syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73921-026
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POVIDONE K30 (UNII: U725QWY32X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73921-026-04	1 in 1 CARTON	04/01/2021	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2021	

Labeler - GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED (860186917)

Establishment			
Name	Address	ID/FEI	Business Operations
GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED		860186917	manufacture(73921-026)

Revised: 3/2021

GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED